

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

TERRY SMITH, M.D. et al.

Serial No.: Not Yet Assigned

Filed: Herewith

For: : DETECTION OF ANTIBODY  
MEDIATED INFLAMMATORY AUTO-  
IMMUNE DISORDERS

)  
) Previous Group Art Unit No. 1644

)  
) Previous Examiner: J. Roark

PRELIMINARY AMENDMENT

Commissioner for Patents  
Washington, D.C. 20231

Sir:

IN THE SPECIFICATION:

Please amend the title as follows:

DETECTION OF ANTIBODY MEDIATED INFLAMMATORY AUTO-IMMUNE  
DISORDERS

On page 1, before 'FIELD OF INVENTION', please insert a new paragraph entitled  
RELATED INFORMATION This application is a continuation of United States Serial No.

OC-94865.1

CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

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October 19, 2001  
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Lynne Fulmer

Name of Person Mailing Paper

*Lynne Fulmer*  
Signature of Person Mailing Paper

09/684,601, filed on October 6, 2000. The priority of this prior application is expressly claimed and the disclosure of this prior application is hereby incorporated by reference in its entirety.

IN THE ABSTRACT:

Please revise the abstract as follows:

The present invention describes a method to detect connective tissue pathologies associated with Graves' disease ophthalmopathy and other antibody mediated inflammatory autoimmune diseases. The detection method comprises obtaining a sample from a patient suffering from an antibody-mediated inflammatory autoimmune disorder and measuring Interleukin 16 (IL-16) or RANTES produced by thyroid associated ophthalmopathy fibroblasts to indicate the presence or severity.

IN THE DRAWINGS:

Formal drawings will be submitted.

IN THE CLAIMS:

Prior to calculation of the fee, please cancel claims 1-19 and add new claims 20-23 as follows:

20. A method of detecting thyroid-associated ophthalmopathy in a patient comprising:
- obtaining a biological sample from the patient, [and ]
- isolating IgG from the patient sample,
- exposing the IgG to orbital fibroblasts from patients with thyroid-associated ophthalmopathy,
- measuring the level of
- IL-16 or
- RANTES produced by the orbital fibroblasts,
- wherein an elevated level of IL-16 or RANTES indicates the presence or severity of thyroid-associated ophthalmopathy in the patient.
21. The method of claim 20 wherein the level of IL-16 or RANTES is measured by an Enzyme-Linked Immunosorbent Assay (ELISA).
22. The method of claim 20 wherein the patient is human.

23. The method of claim 20 wherein the biological sample is selected from the group consisting of:

blood,

urine,

synovial fluid,

ascites,

tissue.

1004651-101001

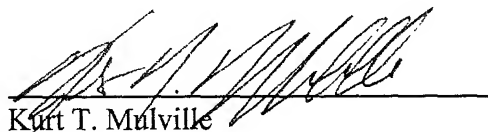
The present application is filed to correct inventorship to add Dr. William Cruikshank as provided by MPEP Section 201.03. The amendment to the claims and specification addresses items raised by the Examiner in the action in the parent application. An additional response to address prior art issues raised in the Action will be submitted in this continuing application.

Respectfully submitted,

LYON & LYON LLP

Dated: October 19, 2001

By:



Kurt T. Mulville

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please amend the title as follows:

[A NOVEL THERAPY FOR] DETECTION OF ANTIBODY MEDIATED  
INFLAMMATORY AUTO-IMMUNE DISORDERS

On page 1, before 'FIELD OF INVENTION', please insert a new paragraph entitled  
RELATED INFORMATION This application is a continuation of United States Serial No.  
09/684,601, filed on October 6, 2000. The priority of this prior application is expressly claimed and  
the disclosure of this prior application is hereby incorporated by reference in its entirety.

IN THE ABSTRACT:

Please revise the abstract as follows:

The present invention describes a method to detect [novel therapy to modulate the]  
connective tissue pathologies associated with Graves' disease ophthalmopathy and other antibody  
mediated inflammatory autoimmune diseases. The [therapy] detection method comprises obtaining  
[administering to] a sample from a patient suffering from an antibody-mediated inflammatory  
autoimmune disorder and measuring [an] Interleukin 16 (IL-16) [activity inhibitor and/] or [a]  
RANTES produced by thyroid associated ophthalmopathy fibroblasts to indicate the presence or  
severity. [activity inhibitor in order to decrease the proliferation of CD4-bearing leukocytes at the  
site of the disease. An especially preferred IL-16 activity inhibitor for use in the therapeutic methods  
of the present invention is rapamycin, and an especially preferred RANTES inhibitor for use in the  
present invention is compound PD098059]